K071406

510(k) Summary of Safety and Effectiveness

SUBMITTER:	United States Surgical, a division of Tyco Healthcare Group LP 150 Glover Avenue Norwalk, CT 06856 Tel. No.: (203) 492-5000 Fax No.: (203) 492-5029
	NOV 2 1 2007
CONTACT PERSON:	Jennifer Brennan Manager, Regulatory Affairs
DATE PREPARED:	February 21, 2007
TRADE/PROPRIETARY NAME:	Autosuture™ ENDO CLIP™ III 5mm Clip Applier
COMMON/USUAL NAME:	Implantable Clip
CLASSIFICATION NAME:	Implantable Clip
PREDICATE DEVICE(S):	Autosuture™ ENDO CLIP™ III 5mm Clip Applier (K061288)
DEVICE DESCRIPTION:	The Autosuture™ ENDO CLIP™ III 5mm Clip Applier contains 18 titanium clips. The applier is designed for introduction and use through an appropriately sized Trocar sleeve, or larger with the use of a converter. The ENDO CLIP™ III 5mm Clip Applier consists of a trigger handle, shaft rotation knob, clip counter window and a 33 cm shaft with jaws at its distal end. Squeezing the handle places a titanium clip in the jaws and closes the jaws to close the clip on the vessel or structure.
INTENDED USE:	The Auto Suture™ Endo Clip III™ 5mm Clip Applier is primarily indicated for patients undergoing laparoscopic surgical procedures involving dissection and occlusion of blood vessels, ducts and other tubular structures, and for radiographic markings.
TECHNOLOGICAL CHARACTERISTICS:	The Autosuture™ ENDO CLIP™ III 5mm Clip Applier is identical to the predicate device. The only change is the inclusion of "manipulation of tissue and the dissection of blood vessels and other tubular structures" to the general indications for the Autosuture™ ENDO CLIP™ III 5mm Clip Applier.
MATERIALS:	All components of the Autosuture™ ENDO CLIP™ III 5mm Clip Applier are comprised of materials which are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	In-vitro and in-vivo animal tests were performed to support the inclusion of "manipulation of tissue and the dissection of blood vessels and other tubular structures" to the general indications for the Autosuture™ ENDO CLIP™ III 5mm Clip Applier.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

United States Surgical
% Ms. Jennifer Brennan
Manager, Regulatory Affairs
150 Glover Avenue
Norwalk, Connecticut 06856

NOV 2 1 2007

Re: K071406
Trade/Device Name: Autosuture™ ENDO CLIP™ III 5 mm Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP, GDO
Dated: October 24, 2007
Received: November 15, 2007

Dear Ms. Brennan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071406

Indications for Use

510(k) Number (if known): K071406

Device Name: **Autosuture™ ENDO CLIP™ III 5 mm Clip Applier**

Indications for Use:

The Auto Suture™ Endo Clip III™ 5mm Clip Applier is primarily indicated for patients undergoing laparoscopic surgical procedures involving dissection and occlusion of blood vessels, ducts and other tubular structures, and for radiographic markings.

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071406

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)